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Via Email and Hand Delivery

Hon. Shira A. Scheindlin
United States District Judge
U.S. District Court, Southern District of New York
500 Pearl Street
New York, New York 10007

Re: *City of New York v. ExxonMobil*, 04 CV 3417 (SDNY)
Motion to Strike Testimony of Dr. Sandra Mohr

Dear Judge Scheindlin:

The City moves to strike the expert testimony of Exxon's witness Dr. Sandra Mohr as unreliable, unsupported by scientific evidence, and beyond the scope of her expert report and deposition. Her opinions that MTBE is not carcinogenic in humans and that neither mutagenicity nor DNA adducts bear any relevance to human disease are contrary to existing science and contrary to the documents she cited as evidence. Other parts of her testimony were also demonstrably false.

Under Rule 702 of the Federal Rules of Evidence, the testimony of an expert must be based on "scientific knowledge" and is admissible only where (1) the testimony is based upon sufficient facts or data; (2) the testimony is the product of reliable principles and methods; and (3) the witness has applied the principles and methods reliably to the facts of the case. Fed. R. Evid. 702; *see Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 595 (1993).

"[W]hen an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony." *Amorgianos v. National R.R. Passenger Corp.*, 303 F.3d 256, 266 (2d Cir. 2002). Because the opinions Dr. Mohr testified to at trial were not supported by adequate scientific foundation, those opinions are unreliable, inadmissible, and must be excluded. Therefore, the City requests that Dr. Mohr's testimony be stricken from the record and that the jury be instructed to disregard her testimony.

DR. MOHR'S TESTIMONY IS NOT SUPPORTED BY THE LITERATURE SHE RELIED ON AT TRIAL AND SHOULD BE STRICKEN FROM THE RECORD

At trial, Dr. Mohr offered opinions on the mutagenicity and carcinogenicity of MTBE that were both beyond the scope of her report and without a solid foundation in the scientific literature on which she purported to rely. Her direct testimony, excerpts of which are attached hereto as Exhibit 1, included the following statements:

- "I have an opinion that MTBE is not carcinogenic in humans." (Trial Transcript ("TT") 3087:1)
- Mutagenicity has "[l]ittle to no relevance" to carcinogenicity in humans (TT 3098:15-18), and "little to no relevance in human disease." (TT 3097:23)
- "There are several studies out there looking at DNA adducts, and they do not correlate with disease…" (TT 3108:7-9)

All three of these opinions are unsupported by the literature on which Dr. Mohr purports to rely. Dr. Mohr stated at trial that "[t]here is no human data that MTBE is a carcinogen, and there is very limited animal data." (TT 3055:14-15) But a document on which Dr. Mohr relies, the U.S. EPA's December 1997 Drinking Water Advisory on MTBE (EPA 1997), excerpts of which are attached hereto as Exhibit 2, reviewed the animal data available at the time and concluded that "[t]he carcinogenicity data *support* a conclusion that MtBE poses a potential for carcinogenicity to humans at high doses." (Exhibit 2 at p. 4, emphasis added.) Furthermore, the EPA never said that low doses of MTBE were *not* carcinogenic – it said only that "[t]he data do not support confident, quantitative *estimation of risk* at low exposure due to the limitations described above." (*Id*, emphasis added.)

Dr. Mohr's testimony also referred to the August 2000 Toxicological Review and Criteria for Evaluation of Exposure to Methyl Tert-Butyl Ether in Drinking Water prepared by the New York State Department of Health (NYSDOH 2000), attached hereto as Exhibit 3. But this document does not support the conclusion that MTBE is not carcinogenic either. Instead, the document stated that MTBE had "caused cancer in laboratory animals" (Exhibit 3 at p. iii) and that "the identification and evaluation of the potential human health effects from long-term exposure to MTBE in drinking water are based on the results of animal studies." (*Id.* at p. ii.) The document also concludes that "[w]hether or not MTBE causes cancer in humans is unknown." (*Id.* at 51.) It does *not* conclude that MTBE is not a human carcinogen.

Dr. Mohr also testified at trial that she reviewed New York's Toxicological Review (Exhibit 3) and in particular "the results of testing for genetic effects of MTBE." (*See* TT 3103:22-3104:10.) But the document does not support Dr. Mohr's conclusions about the mutagenicity of MTBE – neither that MTBE "may not be particularly mutagenic at all" (TT 3104:20-21), nor that mutagenicity bears little relevance to carcinogenicity. In fact, the New York report noted particularly that "MTBE induced changes indicative of DNA damage in three of four mutation tests using lymphoid cells . .

. The activity in lymphoid cells is *particularly relevant given the increased incidence of lymphomas/leukemias* in female rats exposed to oral doses of MTBE (Belpoggi et al., 1995, 1998)." (Exhibit 3 at 30, emphasis added.)

The New York report also highlights the lack of support for Dr. Mohr's opinion that DNA adducts are irrelevant. As the report points out, MTBE "was mutagenic the only time it was tested in a *Salmonella* strain (TA 102) with a functioning DNA excision repair system." (Exhibit 3 at 30). "The results support the hypothesis of Williams-Hill and colleagues that the carcinogenic activity of MTBE may be dependent upon a functional excision repair system *that attempts to remove alkyl adducts* and/or oxidative base damage caused by direct interaction of MTBE or by its metabolites with DNA." (*Id.*) In other words, experimental research supports the theory that MTBE causes cancer by causing genetic mutations that are mediated by the formation of DNA adducts.

The two Chinese studies Dr. Mohr referred to on the stand (TT 3106:1-3107:24) also contradict Dr. Mohr's opinion as to the relevance of DNA adducts. The 2007 study by Yuan et al., included as Tab 18 in ExxonMobil's binder of demonstratives used during Dr. Mohr's examination (and attached hereto as Exhibit 4), explains that "in most cases *DNA adduct level is positively correlated* with the genotoxicity and hence the carcinogenicity of the chemicals (Ottender and Lutz, 1999)." (Exhibit 4 at p. 634, emphasis added.) The 2005 study by Du et al., included as Tab 19 in ExxonMobil's binder (and attached hereto as Exhibit 5), explains that "[w]hen genotoxicity assays and carcinogenicity experiments of a chemical show an inconsistent combination of positive and negative results, *direct investigation of DNA adduction is necessary or very helpful* for assessing whether the test compound is a genotoxin." (Exhibit 5 at p. 398, emphasis added.) Dr. Mohr claims that studies of DNA adducts "just plain haven't panned out." (TT 3108:15.) But there is a vast analytical gap between the evidence Dr. Mohr points to and the conclusions she reaches.

The relevance of DNA adducts to questions of mutagenicity and carcinogenicity is reaffirmed by the U.S. EPA itself, which in its 2005 Guidelines for Carcinogen Risk Assessment (excerpts of which are attached hereto as Exhibit 6) points out that:

> It is *well known* that many carcinogens are electrophiles that interact with DNA, resulting in *DNA adducts* and breakage (referred to in these cancer guidelines as direct DNA effects). Usually during the process of DNA replication, these DNA lesions can be converted into and fixed as mutations and chromosomal alterations that then may *initiate and otherwise contribute to the carcinogenic process* (Shelby and Zeiger, 1990; Tinwell and Ashby, 1991; IARC, 1999). Thus, studies of mutations and other genetic lesions continue to inform the assessment of potential human cancer hazard and in the understanding of an agent's *mode of carcinogenic action.*

Exhibit 6 at p. 2-31, emphasis added.

"[I]n order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation-i.e., 'good grounds,' based on what is known." *Daubert*, 509 U.S. at 590. Contrary to Dr. Mohr's testimony at trial, "[t]he *consensus opinion* (Table 14) is that MTBE is an animal carcinogen because it caused lymphomas/leukemias in female rats, kidney tumors and Leydig cell adenomas in male rats, and hepatocellular tumors in mice." (Exhibit 3 at 31, emphasis added.) Dr. Mohr's opinions that MTBE is not a human carcinogen, that mutagenicity bears little relevance to carcinogenicity, and that DNA adducts have no relationship to human disease are supported by none of the scientific and government agency literature to which she cited in her report or on the stand. Indeed, many of the documents Dr. Mohr relied on state the opposite of her conclusions. The resulting "analytical gap" renders Dr. Mohr's testimony unreliable and inadmissible under *Daubert* as well as *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered").

Dr. Mohr's Statements Regarding FDA Approval of MTBE and the IARC's Classification of MTBE Are False

Dr. Mohr stated during her direct testimony at trial that "MTBE has received experimental approval from the Federal Drug Administration [sic] to use as a medication, as a medication to dissolve gallstones." (TT 3084:8-10.) She also stated in her expert report (attached hereto as Exhibit 7) that MTBE has received FDA approval for use as a human medication to dissolve gallstones (Exh. 7 at 5), a statement demonstrated to be false during Dr. Mohr's cross-examination at trial. (TT 3115:15-22.) "The Food and Drug Administration has *classified*" – not approved – "MTBE as an investigational new drug," (TT 3113:22-25, emphasis added) and did *not* grant approval for use as a human medication. In fact, the FDA defines "investigational or experimental drugs" as "new drugs that have *not* yet been approved by the FDA." (TT 3114:24-3115:1.)

Dr. Mohr also falsely characterized the conclusions reached by the International Agency for Research on Cancer (IARC) and reported in Volume 73 of IARC Monographs on the Evaluation of Carcinogenic Risks to Humans (excerpts of which are attached hereto as Exhibit 8) during her direct testimony. Dr. Mohr was asked, "has IARC classified MTBE as a human carcinogen?" and in response claimed, incorrectly, that "IARC says that MTBE *is not* a human carcinogen." (TT 3096:9-11, emphasis added.) But in fact, IARC concluded that MTBE "is *not classifiable* as to its carcinogenicity in humans," given the limited evidence available at the time of MTBE's carcinogenicity in animals. (Exhibit 9 at p. 375.) The IARC therefore placed MTBE in its Group 3, a category of chemicals for which limited evidence of carcinogenicity is available, rather than in Group 4, which includes chemicals that are *not* carcinogens. (Exhibit 9 at pp. 26-27.)

Because Dr. Mohr's statements about FDA approval of MTBE and IARC's classification of MTBE are demonstrably false, those statements and all related

testimony, should be stricken from the record and the jury should be instructed to disregard them.

Dr. Mohr's Opinions Exceed the Scope of Her Expert Report and Prior Testimony

Dr. Mohr's opinion that MTBE is not carcinogenic in humans is not set forth in her expert report. Her expert report states only that no published reports link increased cancers to MTBE exposures, and that the United States Environmental Protection Agency and International Agency for Research on Cancer have not officially classified MTBE as a human carcinogen. (Exh. 7 at 16.) Nor did Dr. Mohr express this opinion in her 2001 deposition in *South Tahoe Public Utility District v. Atlantic Richfield Company et al.*, excerpts of which are attached hereto as Exhibit 10. Instead, she stated at that time that "while it *does* look like MTBE is a rodent carcinogen, how that's going to translate into potency for humans remains to be seen." (Deposition Transcript 113:8-12, emphasis added.)

Nor is Dr. Mohr's opinion that mutagenicity studies have "[l]ittle to no relevance" to carcinogenicity or any other form of disease in humans set forth in her expert report. Her expert report does not state that mutagenicity is *irrelevant*, but that the U.S. EPA believed in 1997 that "the weight of evidence 'indicated that MTBE is not mutagenic." (Exh. 7 at 17.) In fact, the report went on to say that a more *recent* review of genotoxicity assays stated that "mutagenicity in mouse lymphoma cells" had been independently verified. (Exh. 7 at 18.) At no point in her report does Dr. Mohr make the claim she made at trial: that mutagenicity has no relevance to human disease.

Finally, Dr. Mohr's opinion that DNA adducts do not correlate with disease is not stated in her expert report. Instead, she states only that the study of MTBE and DNA adducts relied upon by Dr. Burns "has been criticized in the way it was conducted" and describes the criticism at issue. (Exh. 7 at 18.) Dr. Mohr did not express opinions about either mutagenicity or DNA adducts in her 2001 deposition.

LEGAL STANDARD

Rule 702 renders the district court responsible for ensuring that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert,* 509 U.S. at 589. In *Kumho Tire Co. v. Carmichael,* 526 U.S. 137, 152 (1999), the Supreme Court clarified that, whether a witness's area of expertise was technical, scientific, or more generally "experience-based," Rule 702 requires the district court to serve the "gatekeeping" function of "mak[ing] certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field."

Expert testimony is subject to Rule 403 as well as Rule 702 and "may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury." Fed.R.Evid. 403. The Second Circuit

has pointed out the importance of both rules in evaluating expert testimony: "the Supreme Court, echoed by members of our own court, has noted the uniquely important role that Rule 403 has to play in a district court's scrutiny of expert testimony, given the unique weight such evidence may have in a jury's deliberations." *Nimely v. City of New York*, 414 F.3d 381, 397 (2d Cir. 2005), citing *Daubert,* 509 U.S. at 595 ("'Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 of the present rules exercises more control over experts than over lay witnesses.'" (quoting Jack B. Weinstein, *Rule 702 of the Federal Rules of Evidence Is Sound; It Should Not Be Amended,* 138 F.R.D. 631, 632 (1991))); *United States v. Young,* 745 F.2d 733, 766 (2d Cir.1984) (Newman, *J.,* concurring) (noting that "the very breadth of the discretion accorded trial judges in admitting [an expert] opinion under Rules 702 and 403 should cause them to give the matter more, rather than less, scrutiny. A trial judge should not routinely admit opinions of the sort at issue here and should weigh carefully the risk of prejudice."). Finally, in assessing the admissibility of expert opinion, the Court must weigh its probative value against the danger of unfair prejudice, confusion of the issues, misleading the jury, or waste of time. *See* Fed. R. Evid. 402.

Thus, under Rules of Evidence 402, 403, and 702 as well as *Daubert,* the district court must determine whether the proposed testimony "both rests on a reliable foundation and is relevant to the task at hand," (*Daubert,* 509 U.S. at 597) and must act as "a gatekeeper to exclude invalid and unreliable expert testimony." *Bickerstaff v. Vassar Coll.,* 196 F.3d 435, 449 (2d Cir.1999); *see Malletier v. Dooney & Bourke, Inc.*, 525 F.Supp.2d 558, 565-566 (S.D.N.Y. 2007). Because Dr. Mohr's testimony is unreliable, its probative value is minimal and is substantially outweighed by its potential for unfair prejudice, confusion of the issues and misleading the jury. In this case, the trial court should serve as that gatekeeper and strike Dr. Mohr's invalid and unreliable expert testimony from the record.

Accordingly, the City respectfully requests that Dr. Mohr's testimony be stricken from the record, and that the jury be instructed to disregard her testimony as to the FDA's purported approval of MTBE, the IARC's classification of MTBE, the non-carcinogenicity of MTBE in humans, the relevance of mutagenicity studies to cancer, and the relative weight of evidence pertaining to DNA adducts.

Respectfully submitted,

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Cc: All Counsel via LNFS & Email